

antithrombotic regimen was maintained throughout the whole study period (median 2 years). The primary end point was defined as net clinical outcomes, a composite of major bleeding and major adverse cardiac and cerebral events (MACCE). Propensity score-matching analysis was also performed in 99 patient pairs.

**Results:** The net clinical outcomes of the TAT group was worse than the DAPT group (34.3% v 21.1%,  $p=0.006$ ), which was mainly driven by higher incidence of major bleeding (16.7% vs 4.6%,  $p<0.001$ ), without any significant increase in MACCE (22.1% vs 17.7%,  $p=0.313$ ). In multivariate analysis, the TAT was an independent predictor for worse net clinical outcomes (HR 1.67; 95% CI 1.09-2.57;  $p=0.018$ ) and major bleeding (HR 3.74; 95% CI 1.74-8.02;  $p=0.001$ ). After propensity score-matching, TAT group still had worse net clinical outcomes, mainly driven by higher major bleeding, than DAPT group.

**Conclusions:** In AF patients undergoing DES implantation, prolonged administration of TAT is associated with worse net clinical outcomes due to the substantial increase in major bleeding without any improvement of MACCE.

#### TCT-476

##### Antithrombotic Therapy In Patients With Chronic Kidney Disease And Atrial Fibrillation Undergoing Percutaneous Coronary Intervention: Results From The AVIATOR Registry

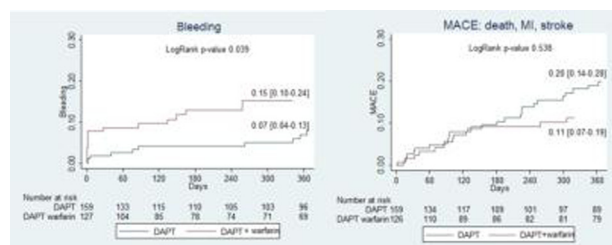
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**Background:** Chronic kidney disease (CKD) confers increased risk for bleeding and ischemic complications after percutaneous coronary intervention (PCI). Guidelines recommend dual antiplatelet therapy (DAPT) in patients undergoing PCI and anticoagulation in patients with atrial fibrillation (AF) and CHADS2 scores  $\geq 2$ . The optimal antithrombotic therapy in patients with CKD and AF after PCI is unknown.

**Methods:** The AVIATOR (Antithrombotic strategy Variability In Atrial fibrillation and Obstructive coronary disease Revascularized with PCI) registry, included 859 consecutive patients with AF treated with PCI, of whom 286 had CKD (e-GFR  $< 60$  ml/min). CKD patients were stratified in 2 groups; triple therapy (TT; warfarin plus DAPT) or DAPT (aspirin plus clopidogrel). Major adverse cardiovascular events (MACE) and clinically relevant bleeding (BARC  $\geq 2$ ) were compared between the groups at one year.

**Results:** Mean age was similar in the 2 groups (76  $\pm$  9 years). Patients receiving TT (n=127, 44.4%) were more often male and had higher ejection fraction compared to patients discharged on DAPT (n=159, 55.6%). Mean CHADS2 scores were identical between groups (3.1  $\pm$  1). MACE incidence at 1-year was similar in the TT vs. DAPT groups (20 vs. 11%,  $p=0.54$ ) but patients on TT tended to bleed more often (15 vs. 7%,  $p=0.04$ ). However, after adjusting for confounding factors the association of TT with increased bleeding was attenuated. (Figure)



**Conclusions:** The most commonly prescribed regimen in these high risk patients with CKD and AF undergoing PCI is DAPT. Patients on TT had similar rates of 1-year MACE but more bleeding compared to those given DAPT.

#### TCT-477

##### Major Adverse Cardiovascular Events And Bleeding Risk Analysis In Elderly Atrial Fibrillation Patients Undergoing Percutaneous Coronary Intervention: The AVIATOR Registry

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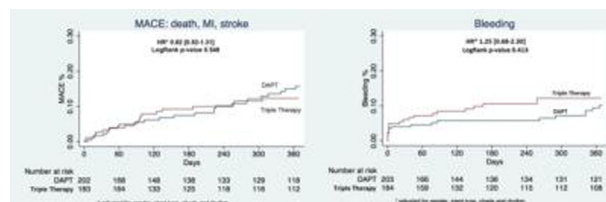
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**Background:** Elderly patients with atrial fibrillation (AF) undergoing percutaneous coronary intervention (PCI) are at an increased risk for bleeding and ischemic complications. Optimum antithrombotic therapy in this group is controversial and challenging.

**Methods:** Among 859 patients from the AVIATOR (Antithrombotic strategy variability in AF and obstructive coronary disease) registry who underwent PCI, 387 patients with age  $\geq 75$  were selected for this analysis. At discharge, these patients were stratified into two groups: those receiving dual antiplatelet therapy (DAPT; aspirin plus clopidogrel), and those receiving triple therapy (TT; DAPT plus warfarin). Major adverse cardiovascular events (MACE) and bleeding rates in these antithrombotic groups were studied after one year.

**Results:** The mean age of patients who received DAPT was 81  $\pm$  4 years, whereas those on TT had a mean age of 80  $\pm$  3 years. Patients receiving DAPT (n=203, 52.5%) were more likely to have a history of bleeding and infarction, while those on TT (n=184, 47.5%) had a past history of stroke. The 1-year MACE (15.7% vs 12.2%, HR 0.82,  $p=0.548$ , for DAPT vs TT, respectively) and bleeding (9.4% vs 12.1%, HR 1.25,  $p=0.413$ , for DAPT vs TT, respectively) rates were similar between the two groups.

**Conclusions:** In contrast to consensus statements, elderly patients with AF undergoing PCI are most frequently treated with DAPT. Bleeding and ischemic complications remain substantial in this cohort irrespective of treatment.



#### TCT-478

##### New Oral Anticoagulants in Cancer Patients Undergoing Percutaneous Endovenous Intervention for Lower Extremity Deep Venous Thrombosis

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**Background:** Development of deep venous thrombosis (DVT) in the setting of cancer portends a poor prognosis. Low molecular weight heparins (LMWH) are considered the standard of care due to their superiority over warfarin. Additionally warfarin resistance is common in cancer patients. The subcutaneous administration of LMWH on a chronic basis is cumbersome and inconvenient. New oral anticoagulants (NOAC) are promising drugs which can simplify long term care of cancer patients with DVT. However little is known on their efficacy in this setting. We therefore sought to evaluate the role of NOAC in patients with cancer-related lower extremity (LE) DVT who received rivaroxaban and apixaban following percutaneous endovenous intervention (PEVI).

**Methods:** PEVI was performed in 50 patients with cancer who had developed extensive symptomatic LE DVT. It was bilateral in 18 patients (36%). At the time of DVT, 15 patients (30%) were on warfarin of whom 7 had therapeutic INR (64%). PEVI was performed within 23  $\pm$  5 hours of admission. All patients received heparin which was stopped after completion of PEVI. Rivaroxaban was initiated at 20 mg daily and apixaban at 5 mg twice daily, 2 hours after PEVI, and continued indefinitely. Warfarin was stopped in all. The mean follow up was 15  $\pm$  4 months. The patients were evaluated for mortality, recurrent VTE and bleeding during this period.

**Results:** There were 5 deaths due to cancer at follow-up. There was no bleeding or recurrent VTE in any patient. All patients tolerated the anticoagulation regimen. The mean duration of hospitalization was 33±4 hours.

**Conclusions:** In patients with cancer associated DVT, Treatment with NOAC following PEVI is highly safe and effective. It leads to shorter hospitalization and no early or late bleeding or recurrent VTE. Patient satisfaction is higher as the inconveniences associated with long term subcutaneous anticoagulation are eliminated.

## Pharmacotherapy - Aspirin, Thienopyridines and other Platelet Inhibitors

**Washington Convention Center, Lower Level, Hall A**  
**Saturday, September 13, 2014, 5:00 PM–7:00 PM**

Abstract nos: 479-506

### TCT-479

#### The Increased Risk of Stent Thrombosis in Acute Coronary Syndromes Is Confined to the First 30 days After PCI: Results from the Multicenter ADAPT-DES Study

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**Background:** The incidence of stent thrombosis (ST) after percutaneous coronary intervention (PCI) is higher among patients with acute coronary syndromes (ACS) compared with stable ischemic heart disease. Whether this incremental increase in the risk of ST is constant over the time after PCI is unknown.

**Methods:** The ADAPT-DES registry prospectively enrolled 8,582 patients with broad inclusion criteria undergoing successful PCI with drug-eluting stents (DES). All patients underwent on-treatment platelet function testing using the VerifyNow assay. We examined adjudicated ST outcomes at prespecified times following PCI among patients presenting with ACS with myocardial infarction (MI, n=2063), ACS with unstable angina (UA) alone (n=2370), and no ACS (n=4149).

**Results:** Patients with MI had the highest platelet reactivity units (PRU): mean 199 vs. 189 for UA vs. 182 for no ACS (p<0.0001 for trend); the incidence of high platelet reactivity defined as PRU>208 was 48.0%, 43.3%, and 39.8%, respectively. Correspondingly higher rates of 2-year definite/probable ST were observed among patients with MI (1.75% vs. 1.13% for UA vs. 0.80% for no ACS, p=0.003). However, the increased incremental risk of ST among MI and UA patients was confined to the early period (first 30 days after PCI: 0.98% vs. 0.42% vs. 0.22%, p=0.0002). The rates of late and very late ST were not significantly different among the 3 groups (Table).

**Conclusions:** Among patients undergoing successful DES implantation, the increased ST risk conferred by the acuity of clinical presentation was confined to the first 30 days after PCI and corresponded with increased on-treatment platelet reactivity.

	ACS with MI	Unstable Angina (ACS without MI)	No ACS	p for trend
Overall ST	1.75%	1.13%	0.80%	0.003
Early ST (0-30 d)	0.98%	0.42%	0.22%	<0.001
Late ST (31 d-1 yr)	0.55%	0.48%	0.30%	0.28
Very Late ST (>1 yr)	0.27%	0.23%	0.31%	0.83

### TCT-480

#### Prior Clopidogrel Therapy in Patients Presenting with Acute Coronary Syndromes (ACS) is Associated with Increase Risk of Stent Thrombosis

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**Background:** Patients sustaining Acute Coronary Syndromes (ACS) despite chronic aspirin treatment, suffer from worse prognosis as compared to aspirin naïve patients. Despite growing use of clopidogrel, data regarding the characteristics and prognostic significance of patients with chronic use of clopidogrel sustaining ACS is limited.

**Methods:** 5386 consecutive ACS patients who were drawn from the 2008, 2010, 2013 ACS Israeli survey (ACSIS) were characterized and followed-up for 30 days. For the purpose of this study major adverse cardiac and cerebrovascular event (MACCE) was defined as death, re-myocardial infarction (MI), stroke and urgent revascularization.

**Results:** Out of 5386 patients, 680 (12.6%) were treated with clopidogrel prior to the index ACS. They were older (66±12 vs. 63±13 p<0.01) and suffered more from diabetes mellitus, hypertension, dyslipidemia as well as prior cardiovascular history, including prior MI, revascularization, coronary artery bypass graft and stroke, although, they were less likely to present with ST elevation MI (21% vs. 45%; p<0.001). Nevertheless, they had more than 2 fold higher incidence of in hospital stent thrombosis (1.6% vs. 0.6%, respectively, p=0.006) and stent thrombosis at 30 days follow-up (2.2% vs. 1.0%, respectively, p=0.007). MACCE rate at 30 days was also higher among chronic clopidogrel treatment patients [15.9 (12.3%) vs. 8.4 (9.4%), p<0.01]. Multivariate log regression model analysis showed that chronic clopidogrel treatment was independent predictors of stent thrombosis [OR=2.6 (95%CI 1.2-5.6)].

**Conclusions:** ACS patients with chronic clopidogrel treatment are at higher risk for in hospital and 30 days stent thrombosis as well as worse prognosis at 30 days.

### TCT-481

#### Two-Year Clinical Results of Patients Randomized to 3- or 12-Month Dual Antiplatelet After Endeavor Zotarolimus Eluting Stent Implantation In OPTIMIZE

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**Background:** Current guidelines recommend prolonged dual antiplatelet therapy (DAPT) consisting of aspirin and a thienopyridine for ≥12 months after drug-eluting stent implantation. However, prolonged DAPT is associated with bleeding complications, and patient compliance and cost can be a barrier. Endeavor zotarolimus-eluting stent (E-ZES) has demonstrated strong safety in short duration DAPT (3 months) analyses but no previous study randomized E-ZES patients to short and prolonged DAPT.

**Methods:** Optimized Duration of Clopidogrel Therapy Following Treatment With the Endeavor Zotarolimus - Eluting Stent in the Real World Clinical Practice (OPTIMIZE) is an open-label, active-controlled, noninferiority study that randomized patients after percutaneous coronary intervention (PCI) 1:1 to 3 or 12 months of DAPT consisting of aspirin (100-200 mg daily) and clopidogrel (75 mg daily). Aspirin was prescribed indefinitely. Eligible patients were those with stable coronary artery disease or history of low-risk acute coronary syndrome undergoing PCI with E-ZES. A total of 3119 patients in 33 sites in Brazil between April 2010 and March 2012 were enrolled and randomized to 3 months (n=1563) or 12 months of DAPT (n=1556). Patients have been followed to 2 years. At 12 months, 3 months of DAPT was noninferior to 12 months for the composite of death, myocardial infarction, stroke, or major bleeding, without a significant increase in stent thrombosis.

**Results:** Two year clinical results will be reported at TCT 2014.

**Conclusions:** This is the first presentation of long-term results in a randomized study of short (3-month) vs. long-term (12-month) DAPT usage after PCI implantation.